UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Civil No. 13-CV-3003 PAM/DTS

United States of America, ex rel. Kipp Fesenmaier,	)	
Plaintiffs,	)	**UNITED STATES' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE COMPLAINT IN INTERVENTION**
v.	)	
The Cameron-Ehlen Group, Inc., dba Precision Lens and Paul Ehlen,	)	
Defendants.	)	

TABLE OF CONTENTS

I. INTRODUCTION

The Complaint in Intervention alleges that Defendants Precision Lens ("PL") and Paul Ehlen ("Ehlen") engaged in conduct that is squarely prohibited by the Anti-Kickback Statute (AKS) and the False Claims Act (FCA). The Complaint presents an archetypal kickback arrangement, alleging that Defendants engaged in a lengthy scheme to pay kickbacks to ophthalmologists in order to induce the physicians to utilize products supplied by PL and its corporate partner in eye surgeries. Defendants provided items of value, such as lavish hunting, fishing and golf trips, private plane flights, and frequent-flyer miles to ophthalmologists. The physicians in turn arranged for ophthalmic products supplied by PL to be used in their cataract surgeries, including those covered by Medicare.

The Complaint is replete with specific examples of Defendants' scheme. It lays out in detail various doctors who received various benefits, the places they were taken, and the reason they were chosen to receive these benefits. It discusses the account that PL referred to as a "slush fund" or a "secret fund," and how it was used to finance some of the trips. It discusses the fair market value of the trips, many of which cost thousands of dollars. It provides the dates and amounts of Medicare claims submitted by several of the physicians who received the trips over the course of many years, and breaks those claims into facility fees and professional fees. It includes representative examples of Medicare claims that were tainted by the kickbacks. It provides several sources of support for the idea that Defendants knew what they were doing was wrongful. The law requires no more at this early stage.

Defendants' Motion to Dismiss raises various hyper-technical arguments that depend on a narrow and often unfounded interpretation of the AKS and FCA. Because the case law and legislative history mandate a broad construction of the AKS, this Court should deny Defendants' motion.

II. LEGAL BACKGROUND

A. False Claims Act

The FCA is "the Government's primary litigative tool for combating fraud." S. Rep. No. 99-345, 99th Cong., 2d Sess. 2, *reprinted in* 1986 U.S.C.C.A.N. 5266. In enacting the FCA, "Congress wrote expansively, meaning 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.' " *Cook County, Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)).

The FCA, among other things, imposes civil liability upon any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C.§ 3729(a)(1)(A), or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).[1] Liability attaches regardless of whether the defendant files the false claim, or causes another to do so. The term "claim" under the Act means "any request or demand,

[1] These citations are to the Fraud Enforcement and Recovery Act of 2009 ("FERA") version of the FCA after it was amended in 2009. Public Law 111-21. The corresponding citations in the pre-FERA version are 31 U.S.C. § 3729(a)(1) and (a)(2), respectively. Both apply to this case depending on the time period, but the result is the same under either version.

whether under a contract or otherwise, for money or property" from the United States. *Id*. § 3729(b)(2).

The FCA defines "knowingly" as "actual knowledge," "reckless disregard," or "deliberate ignorance" of truth or falsity, and expressly "require[s] no proof of specific intent to defraud." *Id*. § 3729(b)(1). A false claim is "material" if it has a natural tendency to influence, or is capable of influencing, the government's payment decision. *Id*. § 3729(b)(4); *see also Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002-03 (2016). A person who violates the FCA is liable to the United States for civil penalties and three times the amount of the government's damages. 31 U.S.C. § 3729(a)(1).

B. Anti-Kickback Statute

The AKS provides, in pertinent part:

> **(2)** whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> > **. . .**
> > **(B)** to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony ….

42 U.S.C.A. § 1320a-7b. The definition of "federal health care program" includes Medicare. 42 U.S.C. § 1320a-7b(f).

Congress adopted the AKS to "strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the [M]edicare and [M]edicaid

programs." H.R. Rep. No. 95-393, at 1 (1977). It was enacted to protect Medicare and Medicaid from increased costs and abusive practices that result from providers making decisions based on self-interest rather than more appropriate patient-related factors. *United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015). One purpose of the statute is to preserve competition. *Id.*

The substantial penalties available under the AKS reflect its significance as a critical tool in combating health care fraud. *See* H. Rep. No. 95-393, at 44 (making violations of AKS a felony, and explaining that fraud in federal health care programs "cheats taxpayers who must ultimately bear the financial burden of misuse of funds in any government-sponsored program" and "diverts from those most in need … scarce program dollars that were intended to provide vitally needed quality health services").

III. SUMMARY OF FACTUAL ALLEGATIONS

PL is a distributor of intraocular lenses ("IOLs") and other products related to ophthalmic surgeries. Complaint in Intervention ("Compl.") ¶ 11. Paul Ehlen is the founder and majority owner of PL. *Id.* ¶ 12. Defendants Ehlen and PL engaged in a lengthy scheme to pay kickbacks, primarily to ophthalmologists, in order to induce the kickback recipients to utilize products supplied by PL and its corporate partner, Sightpath Medical, Inc. ("Sightpath") in eye surgeries. *Id.*¶ 3.

PL provides ophthalmic supplies and equipment to ophthalmologists and facilities for use in various ophthalmology procedures, including cataract-related surgeries. Compl. ¶ 38. Each cataract surgery requires the implantation of an IOL and also involves the

utilization of viscoelastic materials and other surgical supplies (viscoelastics, IOLs and other supplies will be referred to collectively as "Surgical Supplies"). *Id.*

PL understands that the ophthalmologists performing the ophthalmic surgeries are quite influential in determining which products to use in various surgeries, including whether to purchase those products from PL. Compl. ¶¶ 42, 55. PL and Ehlen therefore targeted physicians with their marketing efforts, both directly and through PL's corporate partner Sightpath. *Id.* ¶ 42.

For years, Defendants used illegal kickbacks, such as expensive trips, in order to persuade physicians to purchase products from PL and Sightpath, in connection with eye surgeries paid for by Medicare and other payers. Compl.¶ 56. The trips included lavish hunting, fishing and golf trips. *Id.* ¶ 3. Defendants also provided private flights and frequent flyer miles to physicians, both for free or at heavily discounted rates, in order to induce the physicians to work with PL and Sightpath. *Id.* ¶ 56(b) and (c). Additionally, PL paid for expensive meals and entertainment. *Id.* ¶ 56(d).

During the Complaint's Relevant Time Period ("RTP"), 2006-2015, Ehlen belonged to multiple private clubs and had access to other desirable locations. Compl.¶¶ 6, 58-62. He also had an ownership interest in private planes that could be used to transport physicians to various exotic locations. *Id.* ¶¶ 56, 63, 75, 105-106. Ehlen and PL took a number of physicians on trips to Ehlen's private clubs and various other locations during the RTP. ¶¶ 64-65. PL created and used an account that it referred to as a "slush fund" or a "secret fund" in order to finance some of the trips. *Id.* ¶ 67. The physicians then performed cataract surgeries that were billed to Medicare; for many of those surgeries, the

physicians implanted IOLs and other Surgical Supplies distributed by PL. *Id.* ¶¶ 66, 200-225.

For example, Defendants utilized kickbacks to regain the business of Dr. Richard D. after losing it. Compl. ¶¶ 85-103. PL and Ehlen provided Dr. D. with trips, frequent flyer miles, and other items of value in order to induce him to use PL Surgical Supplies and equipment for his cataract surgeries. *Id.* ¶ 84. They successfully induced him to bring his business back to PL in 2011 after he had stopped using PL in 2009. *Id.* ¶¶ 85-103. After converting Dr. Richard D. back to PL in 2011, PL continued to provide him remuneration to retain his business. *Id.* ¶¶ 103, 57, 84, 144. Likewise, Defendants used private flights to premier sporting events, expensive dinners and other luxurious trips to induce Dr. Kurt W. to increase his ordering from PL and to order IOLs that were more profitable for PL. *Id.* ¶ ¶ 104-116. As a result of their considerable efforts, they succeeded on both fronts. *Id.* ¶ *Id.* ¶ 116. PL received a nearly five-fold annual increase in revenue from Dr. W. from 2008 to 2013, and his deluxe IOL purchases went from 0 in 2008 to 785 in 2013. *Id.* Both Dr. D. and Dr. W. submitted claims to Medicare, using Surgical Supplies supplied by PL, that were rendered false by the kickbacks. *Id.* ¶¶ 200-209.

IV. ARGUMENT

A. RULE 12(b)(6)

In deciding a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), courts assume all facts in the complaint to be true and construe all reasonable inferences from those facts in the light most favorable to the plaintiff. *Morton v. Becker*, 793 F.2d 185, 187 (8th Cir. 1986). A court need not accept as true wholly conclusory allegations, *Hanten v. Sch. Dist.*

of Riverview Gardens, 183 F.3d 799, 805 (8th Cir. 1999), or legal conclusions drawn by the pleader from the facts alleged. *Westcott v. City of Omaha*, 901 F.2d 1486, 1488 (8th Cir. 1990). A court may consider the complaint, matters of public record, orders, materials embraced by the complaint, and exhibits attached to the complaint in deciding a motion to dismiss under Rule 12(b)(6). *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999).

To survive a motion to dismiss, a complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 547 (2007). Although a complaint need not contain "detailed factual allegations," it must contain facts with enough specificity "to raise a right to relief above the speculative level." *Id.* at 555. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 555). In sum, this standard "calls for enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [the claim]." *Twombly*, 550 U.S. at 556.

1. <u>The Complaint States a Claim under the AKS and FCA.</u>

The Complaint lays out a kickback arrangement that violates the AKS and FCA. It presents a traditional AKS theory, where Defendants provide inducements to individuals they believe can generate business, including federal program business. As pertinent here, the AKS requires that Defendants 1) knowingly and willfully 2) pay remuneration 3) to induce a person to 4) "purchase, lease, order, or arrange for or recommend purchasing,

leasing, or ordering any good, facility, service, or item [paid for by Medicare]." 42 U.S.C.A. § 1320a-7b. Each requirement is satisfied here.

a. Knowingly and willfully

The parties agree that in order to meet the AKS' knowing and willful standard, the government need only show that Defendants knew their conduct was wrongful, not that they specifically intended to violate the AKS. *United States v. Jain*, 93 F.3d 436, 440 (8th Cir. 1996); *U.S. ex rel. Health Dimensions Rehab., Inc. v. RehabCare Grp., Inc.*, No. 4:12CV00848 AGF, 2013 WL 4666338, at *4 (E.D. Mo. Aug. 30, 2013); Defs.' Memorandum, Docket #131 ("Brief") at 23; 42 U.S.C. § 1320a-7b(h) (specific intent not required). "Wilfulness… may be inferred from circumstantial evidence. …Ordinarily, it is reasonable to infer that a person intends the natural and probable consequences of conduct knowingly undertaken or knowingly omitted." *United States v. Wetzel*, 514 F.2d 175, 177–78 (8th Cir. 1975).

Here, the Complaint specifically alleges that Defendants knew that it was wrongful and violative of the law to provide these items of value in order to induce the recipients to utilize PL's and Sightpath's products and services. Compl. ¶ 4. Ehlen stated in 2004 that the AKS prohibited PL from providing inducements to ophthalmologists. *Id.* ¶ 178. The Relator, Kipp Fesenmaier, a former Sightpath executive, was involved in planning meetings for some of the trips in 2004 and 2005. *Id.* ¶ 164. He remembered that the focus of the discussion was on selecting high-volume PL customers that PL wanted to maintain, and potential customers with whom PL hoped to increase its market share. *Id.* He remembered that the group of potential trip attendees was narrowed based on current

volume and desired future volume. *Id.* He understood that the physician selection process was intended to be a secret. *Id.* ¶ 166.

Moreover, the Complaint alleges that Defendants used a fund that they themselves referred to as a "slush fund" or "secret fund" to take doctors on trips and conceal their behavior. ¶¶ 5, 67-83. These allegations more than sufficiently allege Defendants knew their conduct was wrongful. *See United States v. Starks*, 157 F.3d 833, 839 n.8 (11th Cir. 1998) (finding evidence of willfulness sufficient where the government's evidence included the "furtive methods" by which the kickback recipients were paid, to indicate that defendants knew they were breaking the law); *United States v. Williams*, 218 F. Supp. 3d 730, 736-37 (N.D. Ill. 2016) (behavior consistent with trying to keep arrangements secret was consistent with finding of willfulness).

In January 2007, PL executives discussed internally a recent kickback settlement involving entertainment practices. Compl. ¶ 179. At a meeting later that year, PL sought to understand how one of its main competitors "gets away with paying for customer trips," and PL's CFO agreed to look into the question. *Id.* The inference is clear: PL wondered how another company got away with something that PL knew to be wrongful. At the same time, Defendants were taking their own customers on trips.

PL knew that a number of kickback cases helped give rise to the updated AdvaMed code in 2009. Compl. ¶ 187. One primary supplier required PL to formally agree that it would abide by the prohibitions in the AdvaMed Code; PL, and specifically Ehlen, did so. *Id.* ¶ 183-84. Defendants knew the updated AdvaMed code provided limitations on how companies were permitted to deal with medical professionals, including prohibitions on

paying for any entertainment or recreational event, such as sporting events, golf, skiing, hunting, sporting equipment, and leisure or vacation trips for any non-employee health care professional. *Id.* ¶ 185. PL discussed these prohibitions at a subsequent meeting, and initially agreed to adhere to the AdvaMed restrictions, by cancelling hunting, fishing and other trips, and not providing golf or sports tickets to physicians. *Id.* ¶ 188. But then, notwithstanding its knowledge of the AdvaMed code and the AKS, and a specific discussion about halting the trips and other forms of remuneration, PL reconsidered that decision and decided to continue the trips for many years. *See, e.g., id.* ¶¶ 95-103; 108-115.

The allegations that Defendants changed their minds and used a "secret" or "slush" fund to pay for the very types of practices they knew AdvaMed and the AKS prohibited (and that they once complained about) further illustrates that Defendants knew what they were doing was wrongful. *See also United States v. Vernon*, 723 F.3d 1234, 1252 (11th Cir. 2013) ("the giving or taking of kickbacks for medical referrals is hardly the sort of activity a person might expect to be legal").

b. Remuneration

Defendants do not challenge the Complaint's allegations that they provided remuneration to physicians. The trips and entertainment provided to doctors are unquestionably remuneration under the AKS. *See,* e.*g., United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1019 n.2 (S.D. Tex. 1998) (reduced rate vacations, hunting trips, and fishing trips), *aff'd*, 125 F.3d 899 (5th Cir. 1997); *United States v. Shaw*, 106 F. Supp. 2d 103, 107-08 (D. Mass. 2000) (hunting trips

and entertainment); *United States v. Medtronic, Inc.*, 189 F. Supp. 3d 259, 271 (D. Mass. 2016) (meals and trips).

c. Inducement

The Complaint alleges that Defendants used remuneration to induce physicians to use PL-supplied products in their surgeries, including Medicare surgeries: "PL and Ehlen, for years, used illegal kickbacks in order to persuade physicians to purchase Surgical Supplies and equipment distributed by PL in connection with eye surgeries, including surgeries paid for by Medicare." Compl. ¶ 56. Defendants targeted the physicians because they understood that the physicians were quite influential, and among the primary decisionmakers, in deciding what Surgical Supplies and equipment they would use in the cataract surgeries, including whether those products would be purchased directly from PL. *Id.* ¶¶ 42, 55.

Defendants accordingly used the trips to induce physicians to "induc[e] them to either begin purchasing IOLs and other Surgical Supplies and equipment from PL and sometimes Sightpath, or to continue doing so." Compl. ¶ 57. They were explicit about their intentions. For example, PL indicated in an internal document relating to one of the private clubs that "this [venue] is expensive so make sure you have your trips planned well, and if you [] don't have docs lined up or they drop out, then cancel your trip. Part of the benefit is just in the asking." *Id.* ¶ 163. The PL customers chosen to receive the miles were almost always ophthalmologists that PL wanted to induce to start, or continue, generating business for PL. *Id.* ¶ 144. PL took Dr. J.S. on two slush fund trips. *Id.* ¶ 75, 80, 83.

Shortly before both, PL discussed a plan with Sightpath to convert Dr. J.S. to an IOL that PL supplied. *Id.* ¶ 76, 78, 82, 167.

Further, the Complaint explains that "Dr. Richard D. received trips, frequent flyer miles, and other items of value from PL and Ehlen for the purpose of inducing him to use PL Surgical Supplies and equipment for his cataract surgeries." *Id.* ¶ 84. Defendants executed a plan to recapture Dr. Richard D.'s business, and his clinic's business, through a series of trips, gifts, dinners and below fair market value ("FMV") frequent flyer miles. *Id.* ¶¶ 85-103. The Complaint also details the efforts PL expended to persuade Dr. Kurt W. to order IOLs from PL, and to convert his business to purchasing deluxe IOLs that were more profitable to PL. *Id.* ¶¶ 104-116.

Defendants' internal discussions make clear that they believed taking doctors on these trips had the power to generate Medicare business. *Id.* ¶ 168 (when PL discussed stopping the trips after agreeing to comply with AdvaMed in 2009, they indicated that they should monitor to see if the change adversely impacted sales); ¶ 169 (crediting the considerable work PL had done to convert physicians to PL's IOLs); ¶ 142 (since frequent flyer miles were so valuable to PL, it resolved to monitor the miles it was providing to customers to make sure providing the miles was generating enough value). The Complaint is explicit about the purpose of Defendants' remuneration: they wanted to persuade the physicians to purchase PL products in connection with their surgeries, including Medicare surgeries.

d. The remunerated physicians caused claims to be submitted that were paid for by Medicare and tainted by Defendants' kickbacks.

Finally, the Complaint alleges that the physicians who were induced to use products supplied by PL in cataract surgeries, including surgeries paid for by Medicare, did, in fact, use those PL-distributed products in surgeries paid for by Medicare. It provides specific examples of physicians who were persuaded by the remuneration Defendants provided to use PL products in their cataract-related surgeries. *See, e.g.*, Compl. ¶ 206 (Defendants successfully persuaded Dr. Richard D. to order the great majority of his cataract lenses from PL in 2011-2015); ¶ 116 (describing Defendants' success in obtaining more of Dr. W.'s business over time and converting more of that business to lenses that were more lucrative for PL). Then the physicians submitted tainted claims to Medicare. Compl. ¶¶ 201-209; *see also* Section IV(B)(2)(b), *infra*. At a minimum, the physicians recommended or arranged for PL-supplied products to be used in Medicare surgeries, which is explicitly prohibited by the AKS. 42 U.S.C.A. § 1320a-7b(2)(B) ("…purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item [paid for by Medicare]"). The statute's inclusion of "arrange for or recommend" encompasses conduct where a non-physician makes a recommendation that needs to be endorsed by a physician. *Mason v. Medline Indus.*, 731 F. Supp. 2d 730, 737 (N.D. Ill. 2010) (motion to dismiss denied where relator alleged that county commissioner was paid "in return for his influence in recommending purchases by county hospitals"); *United States v. Polin*, 194 F.3d 863, 866 (7th Cir. 1999) (Conduct satisfied "recommend" under the statute even though the recommendation had to be endorsed by

the ultimate decisionmaker, a physician). It certainly encompasses decisions made by physicians in their own surgeries, even if others have input into the decision.[2]

2. The Defendants' Arguments Are Contrary to Law and Would Improperly Narrow the Scope of the AKS.

As discussed in the preceding section, the Complaint describes a classic kickback arrangement in painstaking detail, satisfying the AKS and FCA. Defendants raise a number of unsupported legal challenges. There is no additional requirement that the Defendants have a *quid pro quo* arrangement, for example, or that the Defendants focus on only federal program referrals or referrals that will cost the government more.

a. The Complaint alleges an intent to induce referrals, including Medicare referrals

Consistent with the AKS' plain meaning and legislative history, courts have interpreted the statute's prohibitions quite broadly. It is well established that the AKS has been violated if any *one* purpose of the remuneration at issue is to induce referrals, even if other, legitimate purposes for the payment exist. *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) ("If the payments were intended to induce the physician to use Cardio-Med's services, the statute was violated, even if the payments were also intended to compensate for professional services."). The Fifth, Seventh, Ninth, and Tenth Circuits have all echoed the Third Circuit's sound reasoning in concluding that the AKS is violated where one purpose of the remuneration is to induce referrals. *See United States v. Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011) ("Because at least part of the payments to Borrasi was 'intended

[2] In line with the way courts typically describe conduct in AKS cases, this conduct will at times be referred to below as "Medicare referrals."

to induce' him to refer patients to Rock Creek, 'the statute was violated, even if the payments were also intended to compensate for professional services.'") (citing *Greber* at 72); *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000) ("[A] person who offers or pays remuneration to another person violates the Act so long as one purpose of the offer or payment is to induce Medicare or Medicaid patient referrals."); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998).

As discussed above, the Complaint alleges that the purpose of Defendants' scheme was to get the physicians to use PL-distributed products in their cataract surgeries, including in surgeries paid for by Medicare. Defendants argue that their desire to obtain all of a physician's business, rather than solely the Medicare business, somehow insulates them from liability. This is nonsensical.

For example, the Complaint alleges that Defendants pursued Dr. Richard D. over a period of many years, ultimately succeeding in bringing him back into the fold after they had lost his business. By persuading him to use PL-supplied products in the great majority of these surgeries, PL received a large number of Medicare referrals in exchange for the considerable remuneration they provided. Defendants' argument is particularly flawed in this context, since Medicare is estimated to pay for more than 80 percent of cataract surgeries in the United States annually. *See, e.g.*, *Medicare Patients Undergo Unnecessary Tests Before Cataract Surgery, Study Finds*, available at http://www.superdoctors.com/article/Medicare-Patients-Undergo-Unnecessary-Tests-Before-Cataract-Surgery-Study-Finds/007086a9-4aed-4ca0-8c30-26c61bf5d9d7.html.

It is clear from the allegations that one purpose of the remuneration was to induce Medicare referrals. The fact that PL wanted, and successfully obtained, Dr. D.'s non-Medicare business in addition to his Medicare business does not make their conduct less of an AKS violation. *See, e.g.*, *Greber*, 760 F.2d at 69.

Furthermore, CMS' OIG has described its:

> long-standing concern about arrangements pursuant to which parties 'carve out' Federal health care program beneficiaries or business generated by Federal health care programs from otherwise questionable financial arrangements. Such arrangements implicate and may violate the anti-kickback statute by disguising remuneration for Federal business through the payment of amounts purportedly related to non-Federal business.

Advisory Opinion 11-08, p.5, available at https://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn11-08.pdf. In that opinion, CMS expressed concern with arrangements that ostensibly carved out payment for Medicare referrals while providing payment in exchange for other types of referrals. The concern is that the payments for non-Medicare referrals would influence the Medicare referrals. CMS therefore indicated that arrangements that attempted to carve out Medicare referrals could be inappropriate. That being the case, it cannot be the case that a scheme of paying remuneration intended to induce referrals of both Medicare and non-Medicare referrals can somehow be acceptable.

In any event, it was clear that Defendants knew about the AKS (Compl. ¶¶ 176-78), which by its own terms applies to attempts to induce referrals to federal health care programs (*Id.* ¶ 15), and understood that the AKS prohibits providing inducements to referral sources such as opthalmologists (*Id.* ¶¶ 178-80). Defendants accordingly knew that these inducements implicate the federal health care programs.

b. Neither precedent nor legislative history supports the Defendants' cramped construction of the AKS

Defendants attempt to narrow the language of the AKS, contrary to the statute's plain language and legislative history. In adopting the AKS, Congress was mindful of the fact that doctors' "[f]urnishing" of "excessive services" is "relatively difficult to prove and correct," "[s]ince the medical needs of a particular patient can be highly judgmental." H.R. Rep. No. 95-393, at 47. The Senate Report recognized that "claims may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program." S. Rep. No. 99-345 at 9; *see also id.* at 10 (citing *Peterson v. Weinberger*, 508 F.2d 45 (5th Cir. 1975)). The AKS ensures that the government pays only for conflict-free medical care that is provided in the best interests of the patient. *See also United States ex. Rel. Lutz v. BlueWave Health Consultants, Inc. et. al.*, No. 9:14-cv-00230-RMG (D.S.C. May 23, 2018) (ECF No. 910), at 3 ("AKS violations are not technical violations of unnecessarily strict regulatory requirements… Claims that were induced by violations of the Anti-Kickback Statute are serious, so serious that the Government often punishes them criminally.").

Reflecting these principles, courts have held that a Medicare claim is false whenever the claimed medical care was tainted by a kickback because the claim is ineligible for payment, regardless of whether the same claim would have been submitted absent the kickback. "Even if the physician performs some service" in exchange for a kickback, "the potential for unnecessary drain on the Medicare system remains." *Greber*, 760 F.2d at 71. Part of Defendants' scheme was to induce physicians to submit claims to Medicare using

deluxe IOLs, which were more lucrative for PL. The resulting claims are tainted by the kickbacks. This conclusion does not require that Medicare pay more for the claims than it otherwise would have, but simply that the claim was tainted by illicit remuneration. *United States v. Rogan*, 517 F.3d 449, 453 (7th Cir. 2008) (kickback-tainted claims are false because the conditions for payment were not satisfied, and thus it did not matter whether the patients "received some medical care – perhaps all the care reflected in the claims form" or that "if the patients had gone elsewhere, the United States would have paid for their care"). *See also United States v. Millennium Radiology*, 1:11CV825, 2014 WL 4908275, at *7 (S.D. Ohio. Sept. 30, 2014) ("[T]he AKS has been broadly interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for the referral of services or to induce future referrals."); *United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 314 (3d Cir. 2011) ("the Government does not get what it bargained for when a defendant is paid by CMS for services tainted by a kickback.").

Accordingly, Defendants' argument regarding deluxe IOLs is incorrect. Assuming *arguendo* that Medicare pays the same regardless of whether the patient receives a standard IOL or a premium IOL, PL's payment of a kickback to induce the physician to use a PL-supplied premium IOL would still violate the AKS. Defendants' argument relating to the deluxe IOLs also misses an important point: PL wanted doctors to switch to PL-supplied deluxe IOL, potentially away from IOLs supplied by others. As Dr. Kurt W.'s increase in PL purchases indicates, both his PL purchases and his deluxe purchases increased over time. But the AKS does not require this particularized analysis. *Rogan*, 517 F.3d at 453.

Likewise, both the facility fee and professional fee portions of the claims are tainted by the alleged kickbacks, and are therefore not payable. With no case support, Defendants suggest that neither claim was tainted. Brief at 16, 21. There is a reason that no court has adopted a similar argument. If the claims are tainted by a kickback, they are not payable. As another court recently observed in rejecting a similar argument:

> The professional services for which MWS sought reimbursement in this case were to implant the very devices for which Fonn allegedly accepted kickbacks. These services were thus the result of the same financial incentives that colored Fonn's selection of Manufacturer B's and involve the same "underlying transaction," such that Fonn/MWS are not entitled to payment by Medicare and Medicaid for those services.

United States ex rel. Cairns v. D.S. Med. LLC, 1:12CV00004 AGF, 2015 WL 590325, at *5 (E.D. Mo. Feb. 11, 2015). The fact that Medicare breaks out claims into distinct professional and facility fees does not insulate either part of the claim from the AKS. Both are tainted, and both are the foreseeable result of Defendants' conduct.

Nor is there a requirement that Defendants have a *quid pro quo* arrangement with physicians. It is not entirely clear what Defendants mean by this requirement, but it appears that they believe it would require Defendants to expressly precondition trip attendance on making sure that a particular Medicare patient received PL-distributed lenses. This is not the law.

For example, a district court recently stated that:

> "[A] claim is false if it seeks reimbursement for a prescription that was not provided in compliance with the Anti-Kickback Statute, regardless of whether the claim was the result of a quid-pro-quo exchange or would have been submitted even absent the kickback. Relators need not show that a quid pro quo exchange occurred, or that the physicians would not have prescribed Defendant's medication but for the kickbacks. It is sufficient to show that

> Defendant paid kickbacks to a physician for the purpose of inducing the physician to prescribe specific drugs, and that the physician then prescribed those drugs, *even if* the physician would have prescribed those drugs absent the kickback.

United States ex rel. Bawduniak v. Biogen Idec, Inc., 12-CV-10601-IT, 2018 WL 1996829, at *3 (D. Mass. Apr. 27, 2018) (internal citation omitted) (emphasis in original). The plain language of the statute is clear, and makes no reference to requiring a *quid pro quo* arrangement. The Ninth Circuit has held that there is no "basis in the statute, case law, or legislative history to require an agreement to refer program related business." *Hanlester Network v. Shalala*, 51 F.3d 1390, 1396-97 (9th Cir. 1995), superseded by statute on other grounds as stated in *United States v. Elhorr*, 13-20158, 2014 WL 5666213, at *3 (E.D. Mich. Nov. 3, 2014).

Although courts do at times reference the *quid pro quo* language, they do not do so in a way that changes or adds to the requirements of the AKS. For example, the court in *United States v. Reichel* referenced such a requirement but made clear that the one purpose test also applied: "A defendant may act with a mixture of motives and the Government's burden is to prove that part of the remuneration is intended to compensate for past orders and/or induce future orders; but it is not required to prove that such compensation was the only reason for the remuneration." No. 1:15-CR-10324-DPW-1 (D. Mass. June 17, 2016), Doc. 244 at 5-6.

Indeed, it would suffice for the United States to demonstrate that the remuneration was intended in part to compensate for past orders and/or induce future orders. *See also United States v. Omnicare*, 11-CV-8980, 2014 WL 1458443, at *10 (N.D. Ill. Apr. 14,

2014) (allegations that defendant "paid remuneration in exchange for continued business" set out a valid AKS theory). To the extent that a *quid pro quo* label would require something more, the test would no longer be in concert with the law. To the extent that the label requires that one purpose of the remuneration in question is to induce Medicare referrals, that conduct is specifically alleged in the Complaint.

c. The alleged conduct describes more than hope or expectation

As set forth above, the United States has laid out in detail that Defendants intended to, and did induce Medicare referrals, with various examples. Section IV(A)(1)(c), *supra*. Defendants' argument that the United States only alleges a mere hope founders for that reason. Additionally, Defendants' reliance on *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000) is misplaced (Brief at 12-13), as that case supports the United States argument. In *McClatchey*, which provided the genesis for the language Defendants cite, the district court had instructed:

> To offer or pay remuneration to induce referrals means to offer or pay remuneration with the intent to gain influence over the reason or judgment of a person making referral decisions. The intent to gain such influence must, *at least in part*, have been the reason the remuneration was offered or paid. On the other hand, defendants Anderson, Keel, and McClatchey *cannot be convicted merely because they hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes*.

Id. at 834. (italics in original). The defendant argued that this instruction was incorrect, because it did not require that the primary purpose of the remuneration was inducement. *Id.* The court disagreed, as referenced above, and reversed the judgment of acquittal. *Id.* at 835. *See also United States v. Lahue*, 261 F.3d 993, 1008 (10th Cir. 2001) (in a related

appeal by a kickback recipient in *McClatchey*, the court explained that the AKS "allows business relationships between a hospital and physician where the motivation to enter into the relationship is for legal reasons *entirely distinct from the collateral hope for or decision to make referrals*" (emphasis supplied)). Accordingly, these cases simply stand for the "one purpose" intent concept. The situation in the instant case is quite different: at issue here are expensive trips, private flights, expensive sporting events, and the like. This remuneration was designed to induce referrals; it is not plausible to suggest, and Defendants do not argue, that the remuneration was wholly designed for other legal purposes. Indeed, Defendants' intent to induce can be inferred from the great value of this remuneration. *Medtronic*, 189 F. Supp. 3d at 171.

d. FAA regulations do not provide a valid defense

Defendants argue about the cost of the private flights, relying upon the *Flytenow* case. (Brief at 10-11 n.7). They do not argue that a heavily discounted, or free, private plane flight complies with the AKS, but rather suggest that they should be exempted from the AKS requirement because of a separate FAA rule. The government has contemplated specific ways to handle activities that would otherwise violate the AKS, but that public policy dictates should be protected: by promulgating a series of safe harbors. For obvious reasons, there is no safe harbor that allows a company seeking to induce Medicare referrals to take doctors from whom they are seeking business on heavily discounted trips on the company's private plane.

Moreover, Defendants' argument founders on the false premise that they needed to fly ophthalmologists on private flights, and had to make a choice between violating the AKS or an FAA regulation. If PL wanted to entertain its clients (in contravention of AdvaMed) but felt FAA regulations prohibited them from charging a fair market value price for a private flight, the physicians could have simply flown commercially and paid for it themselves.

Finally, Defendants ignore the specific allegations in the Complaint, which render their argument irrelevant. For example, the Complaint alleges that PL took Dr. Kurt W. on a private plane to a college football game that cost the company $25,000 and did not charge him anything, and on another occasion charged him $500 for a trip to a premier golf event for which the flight alone cost the company $20,000. Compl. ¶¶ 105-06, 109-112. These trips constitute illegal remuneration even if Defendants' argument regarding the *pro rata* expenses were accepted, as Dr. W's *pro rata* share would have been much higher than what he paid.

B. RULE 9(b)

1. Fed. R. Civ. P. 9(b) Standard.

"In order to satisfy the pleading requirements of Rule 9(b), 'the complaint must plead such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result.'" *Olson v. Fairview Health Servs. of Minn.*, 831 F.3d 1063, 1070 (8th Cir. 2016) (quoting *U.S. ex rel. Joshi v. St. Luke's Hosp.,*

Inc., 441 F.3d 552, 556 (8th Cir. 2006) (citations omitted). "In other words, 'the complaint must identify the who, what, where, when, and how of the alleged fraud.'" *Id.*

The Eighth Circuit has explained that Rule 9(b)'s overarching purpose is to put defendants on notice of the alleged misconduct so that they can prepare an adequate and timely response. *See United States ex rel. Costner v. United States*, 317 F.3d 883, 888 (8th Cir. 2003); *Abels v. Farmers Commodities Corp.*, 259 F.3d 910, 920-21 (8th Cir. 2001)("The special nature of fraud does not necessitate anything other than notice of the claim; it simply necessitates a higher degree of notice."). All allegations should be taken as true, and all reasonable inferences drawn in the plaintiff's favor. *United States. ex rel. Sandager v. Dell Mktg., L.P.*, 872 F. Supp. 2d 801, 812 (D. Minn. 2012).

"Rule 9(b) 'is context specific and flexible and must remain so to achieve the remedial purpose of the False Claim Act.'" *United States ex rel. Thayer v. Planned Parenthood of the Heartland*, 765 F.3d 914, 918 (8th Cir. 2014) (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009)). As a result, an FCA complaint "can satisfy Rule 9(b) without pleading representative examples of false claims if [it] can otherwise plead the particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* (internal quotations omitted). This approach "fulfills the objectives of Rule 9(b) without stymieing legitimate efforts to expose fraud." *Id.* (internal quotations omitted). To satisfy the "particular details" requirement, the complaint must provide sufficient details "to enable the defendant to respond specifically and quickly to the potentially damaging allegations." *Id.* at 918-19 (internal quotations omitted).

Alternatively, it is well-established in the Eighth Circuit that a plaintiff need only allege "*some* representative examples" of the alleged fraudulent conduct in order to satisfy Rule 9(b). *Joshi*, 441 F.3d at 557 ("[N]either this court nor Rule 9(b) requires [the plaintiff] to allege specific details of every alleged fraudulent claim forming the basis of [the plaintiff's] complaint."). This is particularly true where, as here, the complaint "alleges a systematic practice of submitting fraudulent claims." *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 822 (8th Cir. 2009) (quoting *Joshi*, 441 F.3d at 556-557).[3]

That a complaint alleging violations of the FCA must be pled with particularity pursuant to Rule 9(b) "does not render the general principles of simplicity set forth in Rule 8 . . . inapplicable to pleadings alleging fraud." Charles A. Wright and Arthur Miller, 5 Fed. Pract. & Proc. § 1298. As the Eighth Circuit has long recognized, "Rule 9(b) is to be read in the context of the general principles of the Federal Rules, the purpose of which is to simplify pleading." *Costner*, 317 F.3d at 888; *Abels*, 259 F.3d at 920-21 ("We must interpret the requirements of Rule 9(b) in harmony with the principles of notice pleading.") (internal quotation marks omitted). Indeed, Rule 9(b) expressly states that "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally."

[3] *See also United States ex rel. Onnen v. Sioux Falls Indep. Sch. Dist. #49-5*, No. Civ 07-4174, 2009 WL 4891704, at *2 (D.S.D. Dec. 17, 2009) (holding that complaint gave defendants "sufficient notice of the claim" despite court's observation that it "may not state the particulars of every alleged instance of fraud, . . ."); *United States ex rel. Johnson v. Shell Oil Co.*, 183 F.R.D. 204, 207 (E.D. Tex. 1998) (requiring complaint to contain specific dates and invoice numbers for each transaction "would cause the complaint to be in the hundreds of pages, if not hundreds of pounds.").

2. The Claims Are Sufficiently Pled.

As set forth below, the Complaint fully satisfies Rule 9(b)'s particularity standard. The Complaint alleges – in considerable detail – Defendants' lengthy fraudulent scheme, with numerous details. It provides several years of specific representative examples of cataract surgeries performed with products distributed by Defendants, billed to and paid by Medicare, tainted by kickbacks. Compl. ¶¶ 201-203. It references the facility fee claims and professional fee claims for 38 specific surgeries submitted to Medicare by Dr. Richard D. and his practice in 2009, 2012 and 2014, with the amounts Medicare paid for each. *Id*. And it further explains the effect of the remuneration by highlighting twelve physicians who purchased IOLs and other Surgical Supplies through PL after receiving kickbacks. It provides yearly figures for the amount of PL business these physicians and their corresponding facilities performed, which in some cases increased by over $500,000 from 2007-2014. For these twelve physicians alone, the Complaint alleges that Medicare paid over $15 million in professional fees and over $28 million in facility fees. Indeed, the Complaint's robust allegations satisfy Rule 9(b) even without the representative claims that it included. *See Thayer*, 765 F.3d at 918 (pleading the particular details of a scheme to submit false claims paired with reliable indicia creates a strong inference that claims were actually submitted, without requiring pleading of the actual claims). The Complaint provides enough reliable detail of Defendants' fraudulent scheme, alongside the physicians' Medicare claims information and purchases from PL, to infer that claims were actually submitted to Medicare for all of the physicians who received remuneration, and to enable Defendants to respond.

In short, the Complaint is comprehensive in its description of the illegal conduct, provides representative examples of false claims submitted to Medicare and pleads "when the acts occurred, who engaged in them, and what was obtained as a result." *Olson*, 831 F.3d at 1070. It provides the who, what, when and where required by the Eighth Circuit's 9(b) standard. It alleges a classic kickback scheme in sufficient detail to enable Defendants the ability to respond. *See*, *e.g.*, *Costner*, 317 F.3d at 888; *Joshi*, 441 F.3d at 557.

a. Defendants paid numerous kickbacks to ophthalmologists

From 2004-2014, Ehlen and PL took ophthalmologists on numerous luxury hunting, fishing, golfing, or other leisure trips. Compl. ¶ 64. Defendants had access to desirable luxurious accommodations and destinations, including a private exclusive club in Montana called the Stock Farm Club, an exclusive private club in South Dakota called Sutton Bay, a resort in Lake of the Woods, Ontario called the Big Narrows Resort that Ehlen's family owned, and an ownership stake in hunting land in White Lake, South Dakota. Compl. ¶¶ 57-62. Ehlen and PL made a regular practice of taking physicians to these locations without requiring the physicians to provide market-based reimbursement. *Id.* ¶ 57.

To finance some of these trips, PL created and used an account that it referred to as a "slush fund" or a "secret fund." Compl. ¶ 67. The fund was maintained at PL and used to fund expensive trips involving Sightpath's CEO, Jim Tiffany, and various physicians that the companies did significant business with or hoped to do business with in the future. *Id.* Tiffany primarily requested slush fund money from PL officials. *Id.* ¶ 68. By 2012, PL's Chief Financial Officer Chris Reichert estimated that "PL had provided [Tiffany] with a 'marketing' rebate fund for years where he has hid over $100,000." *Id.* ¶ 71. The Complaint

lists a number of different trips that were funded by the slush fund. *Id.* ¶¶ 72-83, 118-119. It alleges that the trips were motivated by PL's desire to retain the physicians' business or convert them to PL-supplied products. *Id.* ¶¶ 76, 79, 81, 82.

b. The kickbacks induced ophthalmologists to use IOLs and other Surgical Supplies distributed by PL in cataract surgeries

The Complaint alleges that PL and Ehlen's kickback scheme targeted ophthalmologists with their marketing efforts because it knew that they were quite influential in deciding what Surgical Supplies and equipment were used in their surgeries. Compl. ¶¶ 40-42, 55-56. *See also* Section IV(A)(1)(c.), *supra*. It alleges that PL used kickbacks to persuade physicians to purchase Surgical Supplies and equipment distributed by PL in connection with eye surgeries, including surgeries paid for by Medicare. *Id.* ¶ 56. The Complaint uses representative examples of physicians and practice groups that received many of the trips, and lists those physicians' corresponding Medicare claims and ordering behavior from PL: Dr. Richard D. (¶¶ 84-103); Dr. Kurt W. (¶¶ 104-116); and Minnesota Eye Consultants (¶¶ 117-124).

i. Dr. Richard D.

Dr. Richard D. met Ehlen on a PL funded trip in 2004.[4] *See id.* ¶¶ 84-103. Dr. D. is a part owner of Bay Microsurgical Center ("Bay"), which, during the RTP, purchased IOLs from PL for use in cataract surgeries. Compl. ¶ 207. During the RTP, Dr. D. used mostly AMO IOLs in his surgeries. *Id.* ¶ 90. From 2006 through early 2009, he purchased them

[4] Dr. D. went on numerous trips with Ehlen dating back to 2004, including an annual hunting trip to White Lake in one of Ehlen's private planes. Compl. ¶¶ 86-87.

from PL. *Id*. ¶ 91. In 2008, Bay purchased 2,482 IOLs from PL. *Id.* ¶ 207. In early 2009, at AMO's request, Dr. D. began purchasing IOLs directly from AMO rather than PL, and continued to do so until September 2011. *Id.* ¶ 92-93. In 2010, Bay purchased no IOLs from PL. *Id*. ¶ 207.

Defendants used various types of illegal remuneration to persuade Dr. D. to convert his business back to PL. *Id.* ¶ 95. Between October 2010 and December 2011, Defendants took Dr. D. on two hunting trips, paid for a $500 birthday meal, and took him out for another expensive dinner. *Id.* ¶ 96.[5] Further, in 2011, PL proposed that if Dr. D. would agree to implant at least 10,200 cataract lenses purchased from PL over the next three years, PL would give his practice a Zeiss IOL Master machine valued at $30,000. Compl. ¶ 99. Dr. D.'s practice agreed to PL's proposal with a slightly adjusted volume requirement and entered into the arrangement in late 2011. *Id*. ¶ 100.

From late 2011 through the end of 2015, after ordering no IOLs from PL in 2010, Dr. D. ordered the vast majority of his cataract lenses through PL. *Id*. ¶ 101. As a result, in 2011, 2012, 2013, and the first three quarters of 2014, Bay increased its IOL purchases from PL to 1,090, 3,512, 3,814 and 2,845, respectively. *Id*. ¶ 207. Over the same time period, Bay paid PL $117,617, $376,211, $458,793 and $485,209. *Id.*

During the late 2011-2015 period, PL continued to take Dr. D. on trips, and facilitated his personal travel using frequent flier miles, without asking him to pay the fair market value of those trips. *Id.* ¶ 102. Additionally, Defendants took Dr. D. out to a number

[5] Dr. D. paid a portion of the hunting trips, albeit at an amount below FMV. Compl. ¶ 97.

of expensive dinners. *Id.* ¶ 103. The Complaint alleges that PL and Ehlen paid Dr. D. such remuneration to induce his continued purchase of IOLs and other Surgical Supplies and equipment from PL. *See* Compl. ¶ 57.

The Complaint provides specific representative examples of cataract surgeries Dr. D. performed at Bay in 2009, 2012, and 2014, using IOLs supplied by PL, and for which Medicare was billed and made payment. Compl. ¶¶ 201-203.[6] It identifies 38 specific Medicare surgeries, with the facility fee and professional fee claims for each. *Id.* From 2007 through April 2009, Dr. Richard D. billed Medicare for at least 1,091 cataract surgeries using procedure codes 66982 and 66984 and Medicare paid $595,416.37 on these claims and related services, as well as $778,725.23 in corresponding facility fees. Compl. ¶ 205. From October 2011 through 2015, Dr. Richard D. billed Medicare for at least 3,369 cataract surgeries using procedure codes 66982 and 66984 and Medicare paid $1,561,231.55 on these claims and related services, as well as $2,333,977.90 in corresponding facility fees. Compl. ¶ 206.

ii. Dr. Kurt W.

Similarly, Defendants spent a considerable amount of money providing trips and other forms of entertainment to persuade Dr. Kurt W. to do business with PL. Compl. ¶ 104. The Complaint alleges, among other things, that Defendants: (1) treated Dr. W. and his wife to a trip to the national championship college football game in Miami, Florida in

[6] To protect patient privacy, the Complaint lists only patient initials, but the United States provided Defendants comprehensive data, including patient names, dates of service, place of service (all at Bay), and HICN numbers.

2009 via private plane, at an estimated cost of just under $25,000; (2) took Dr. W. to the Stock Farm Club in 2006 and 2008, once with his wife and once with a group of other doctors, without asking him to pay for either trip; (3) flew Dr. W., among a group of ophthalmologists, in one of Ehlen's private planes to the Masters Golf Tournament in Augusta, Georgia at a cost of approximately $20,000 to PL; (4) entertained Dr. W. and other physicians to expensive dinners in January 2010, September 2011, February 2012, and May 2013. Compl. ¶¶ 105-115. Dr. W. steadily increased his business with PL from $137,654 in 2007 to $1,177,228 in the first 3 quarters of 2014. *Id.* ¶ 209. This business included a considerable number of Medicare claims. From 2007 through 2015, Dr. Kurt W. billed Medicare for at least 10,054 cataract surgeries using procedure codes 66982 and 66984 and Medicare paid $4,858,875.07 on these claims and related services, as well as $9,136,004.97 in corresponding facility fees. Compl. ¶ 208.

iii. Minnesota Eye Consultants

Likewise, PL provided considerable financial inducements to one of its largest customers, Minnesota Eye Consultants ("MEC"). Compl. ¶ 117. For example, Defendants took a group of physicians, including Dr. Richard L. of MEC, to Sutton Bay on a private plane and hosted them for Sutton Bay activities from September 18-20, 2009, without charging Dr. L. *Id*. ¶ 119. Similarly, in 2007, PL flew Dr. Elizabeth D. of MEC to New York City on a private plane and paid for her hotel room so that she could attend a Broadway musical with Ehlen and his wife. *Id.* ¶ 120. PL also provided Dr. D. two international trips at below FMV, to Munich in April 2012, and Quebec in September 2012. *Id.* ¶ 121-22. Finally PL and Ehlen paid $1,878 for Dr. D.'s birthday party at a popular

Minneapolis steakhouse, and provided her free or below FMV access to private flights on various other occasions. *Id*. ¶ 123-24.

MEC steadily increased its business with PL from $611,856.14 in 2007 to $1,189,469.71 in the first 3 quarters of 2014. *Id.* ¶ 212. Much of this was Medicare business. From 2007 through 2015, Dr. Elizabeth D. billed Medicare for at least 3,300 cataract surgeries using procedure codes 66982 and 66984 and Medicare paid $1,753,462.11 on these claims and related services, as well as $2,672,927.40 in corresponding facility fees. Compl. ¶ 210. From 2009 through 2015, Dr. Richard L. billed Medicare for at least 687 cataract surgeries using procedure codes 66982 and 66984 and Medicare paid $337,387.94 on these claims and related services, as well as $896,684.77 in corresponding facility fees. Compl. ¶ 211.

iv. Other Physicians and Trips

The Complaint also alleges that PL took a number of other physicians on trips. For many of the physicians, the Complaint provides detail on their corresponding Medicare claims and PL ordering. This detail provides a sense of the magnitude of the claims at issue. Compl. ¶ 200. For other doctors, the Complaint alleges that the physicians were taken on specific trips, but does not reference the specific volume of Medicare claims in given years.[7] The Complaint alleges that for all of the doctors who received the various trips discussed: "These physicians then performed surgery using products supplied by PL and,

[7] In the unlikely event that this Court believes this additional information is required to satisfy Rule 9(b), the United States would respectfully request leave to amend the Complaint to provide the additional detail.

in some cases, Sightpath. The physicians discussed below were PL customers during the RTP who performed cataract surgeries that were billed to Medicare." *Id.* ¶ 66. The Complaint provided comprehensive information for various physicians in addition to those discussed above, including remuneration provided, Surgical Supplies purchased from PL, and Medicare claims data during the RTP:

- Dr. Michael M.: ¶¶ 130-131 (remuneration including hunting trips, private flights, frequent flyer miles, expensive meals, between 2008-2010); 214-215 (Medicare cataract surgeries from 2008-2011, amount Medicare paid on those claims, and amount of Surgical Supplies Dr. M.'s clinic purchased from PL between 2007-2011)

- Dr. Christopher W.: ¶¶ 130-131 (hunting trips between 2008-2010); 213, 215 (Medicare cataract surgeries from 2008-2011, amount Medicare paid on those claims, and amount of Surgical Supplies Dr. W.'s clinic purchased from PL between 2007-2011)

- Dr. Vance T.: ¶¶ 133, 135-140, 145-150 (hunting trips, private flights, frequent flyer miles, between 2004-2014); 216-217 (Medicare cataract surgeries from 2009-2015, amount Medicare paid on those claims, and amount of Surgical Supplies Dr. T.'s clinics purchased from PL between 2007-2014)

- Dr. Matthew H: ¶¶ 126-127 (ski trips in 2010 and 2011); 221; 223 (Medicare cataract surgeries from 2007-2013, amount Medicare paid on those claims, and amount of Surgical Supplies Dr. H.'s clinic purchased from PL between 2007-2013)

- Dr. Kevin F.: ¶¶ 126-127 (ski trips in 2010 and 2011); 222-223 (Medicare cataract surgeries from 2007-2013, amount Medicare paid on those claims, and amount of Surgical Supplies Dr. F.'s clinic purchased from PL between 2007-2013)

- Dr. Douglas E.: ¶¶ 126-127 (ski trips in 2010 and 2011); 220, 223 (Medicare cataract surgeries from 2007-2013, amount Medicare paid on those claims, and amount of Surgical Supplies Dr. E.'s clinic purchased from PL between 2007-2013)

- Dr. David W.: ¶¶ 135-136; 160 (private flights, sporting events, and hunting trips between 2004-2009); 224-225 (Medicare cataract surgeries from 2007-2010, amount Medicare paid on those claims, and amount of Surgical Supplies Dr. W.'s clinic purchased from PL between 2007-2010)

- Dr. Samuel S.: ¶¶ 75-76, 78, 167 (hunting trip in 2008); 218-219 (Medicare cataract surgeries from 2007-2009, amount Medicare paid on those claims, and amount of Surgical Supplies Dr. S.'s clinic paid PL between 2007-2009).[8]

3. Defendants Articulate an Unnecessary and Unreasonably Onerous Rule 9(b) Standard that the Complaint Nevertheless Meets.

As referenced in the preceding section, given the tremendous level of detail provided in the Complaint, not to mention the existence of representative examples of false claims, the United States easily met the Eighth Circuit's standard, set forth in *Thayer*, of providing notice of the alleged misconduct so that Defendants can efficiently respond. *See* 317 F.3d at 888. Yet Defendants make several challenges. Each should be rejected.

First, relying on law from a different circuit, Defendants argue that the government did not meet its pleading standard because it did not allege a long chain of causal links from the conduct to submission of claims. Brief at 21 (citing *Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 914 (6th Cir. 2017)). Defendants specify that the government must allege: (1) PL gave a physician remuneration as part of an illegal *quid pro quo*, (2) that as a result, the physician receiving remuneration caused the facility where he performed a surgery to purchase IOLs from PL; (3) that the physician used a PL IOL in the surgery; and (4) that the surgery was for a Medicare patient and resulted in claims to

[8] Defendants are correct that the United States does not intend to seek damages for claims that preceded the receipt of remuneration. Brief at 20 n. 15. The discussion of Dr. Samuel S. in Paragraph 219, which compared his PL purchases in 2007, 2008 and 2009, indicated why PL felt the need to use the slush fund to take him on an expensive trip in 2008 to retain his business. This is a unique example. As for the idea that there is a finite "end date" after which claims are no longer tainted by a kickback, Defendants do not cite to anything requiring a specific end date. While this issue will be explored as the case progresses, it is not a basis for dismissal.

Medicare. (*Id.* at 21-22.) The Eighth Circuit has not adopted the Sixth Circuit's novel and ill-fitting chain-link 9(b) pleading standard, which at least under PL's characterization would be contrary to law. As discussed above, PL fabricates a *quid pro quo* requirement that does not correctly describe the applicable law. To the extent any type of *quid pro quo* would be read into the statute, the conduct described in the Complaint properly alleges such an arrangement under the governing one purpose test. *See* Section IV(A)(2)(a.), *supra*.

Likewise, the law does not require the United States to prove that the physician submitted the claim to Medicare as a result of the kickback; the legislative history and precedent surrounding the AKS make clear that the breadth of the AKS does not to require such an inquiry into the physicians' decisionmaking. *See id.* Rather, the Complaint must comply with the Eighth Circuit's 9(b) standard, and for the reasons set forth above, it does so.

Regardless, even though not required by Rule 9(b), the Complaint meets the Sixth Circuit's standard for pleading an example of fraud from the beginning of a chain to the end. As set forth above, the Complaint alleges significant remuneration paid by Defendants to Dr. Richard D., in the form of luxury trips and expensive dinners, for the purpose of obtaining his ongoing business and then regaining it after the company lost it. Next, it alleges a corresponding change in Dr. Richard D.'s purchasing behavior, moving his and his facility's business from AMO to PL. Finally, it states specific examples of claims billed to and paid by Medicare for cataract surgeries performed by Dr. Richard D., at Bay Microsurgical Center, using IOLs and related products purchased directly from PL.

Accordingly, the Complaint satisfies even Defendants' hyper-rigorous pleading standard and the government's case should be permitted to proceed. See, e.g., *Omnicare*, 2014 WL 1458443, at *10 (permitting case to move forward based on the allegations and reasonable inferences drawn from them, where complaint described scheme in detail and identified at least some of the major players and the facilities that were offered remuneration in exchange for business).

Next, Defendants contend the Complaint should be dismissed as to all claims that do not involve Dr. Richard D., because the Complaint does not identify specific Medicare claims submitted for each identified physician. (Brief at 22, n. 17.) In essence, Defendants imply that the Complaint alleges 29 separate fraudulent schemes, one for every physician who received a kickback.[9] Defendants offer no case law to support this characterization. In fact, even *Ibanez* contradicts the approach Defendants ask this Court to adopt. There, a national pharmaceutical company allegedly engaged in a complex, nationwide kickback scheme whereby it improperly induced providers to prescribe an antipsychotic drug through remunerations and benefits in violation of the AKS. *Ibanez*, 874 F.3d at 911-12. Although the circuit court held that the complaint did not meet its strict chain-link pleading requirement, it explained: "*a single adequately pled claim* of this nature would allow relators to satisfy Rule 9(b)'s pleading requirement and proceed to discovery *on the entire scheme*." *Id.* at 915 (emphasis added and internal footnote omitted).

[9] To be clear, the list of physicians and trips discussed in the Complaint is not an exhaustive list. Compl. ¶ 65.

The United States has alleged one fraudulent scheme that took place over several years, and need not attach a list of hundreds of false claims to satisfy Rule 9(b). Indeed, the point of allowing pleading by representative example is to avoid such an exercise. Adopting Defendants' proposed pleading standard would therefore require the government to subpoena every physician who received kickbacks from Defendants, along with numerous facilities. Aside from being expressly contrary to the Eighth Circuit's 9(b) standard, this would create significant inefficiencies. Indeed, in cases alleging that a defendant caused third parties to file false claims with the government, like this case, the First Circuit has held that Rule 9(b) may be satisfied by providing "factual or statistical evidence to strengthen the inference of fraud beyond possibility without necessarily providing details as to each false claim. *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L. P.*, 579 F.3d 13, 29 (1st Cir. 2009) (quotations omitted). The government has provided numerous examples of physicians who received remuneration, were thereby induced to (at least) recommend or arrange the purchase of PL-supplied products, and submitted Medicare claims including those products. The government has satisfied 9(b).

Relatedly, Defendants contend that the Complaint fails to allege that the identified doctors were the decisionmakers at their respective facilities. First, this is inaccurate, as described in Section IV(A)(1)(c.) above. This is confirmed by the ordering behavior of Dr. Richard D. and Dr. Kurt W., particularly in light of the reasonable inferences to which the government is entitled. Second, the conduct prohibited by the AKS requires only that the

physicians be in a position to recommend or arrange the use of PL products. *See* Section IV(A)(1)(d.), *supra*.[10]

C. STATUTE OF LIMITATIONS

There is a longstanding rule that statutes of limitations should be interpreted in the government's favor, rooted in the traditional rule that "the sovereign is given the benefit of the doubt if the scope of the statute is ambiguous." *BP Am. Prod. Co. v. Burton*, 549 U.S. 84, 96, 127 S. Ct. 638, 646 (2006). "[P]recedent clearly hold[s] that no statute of limitations will block federal government actions unless Congress clearly and specifically says so." *Capozzi v. United States*, 980 F.2d 872, 875 (2d Cir. 1992). FCA defendants bear the burden of establishing that the Government's claims are barred by the statute of limitations. *See, e.g., United States v. Carell*, 681 F. Supp. 2d 874, 883 (M.D. Tenn. 2009).

Under 31 U.S.C. 3731(b)(2), FCA suits may be brought within six years of the date of the violation or within three years of the date the Government learns of its right of action, whichever deadline occurs last, as long as the action is brought within ten years of the violation. 31 U.S.C. 3731(c) provides that "[f]or statute of limitations purposes, any [Government Complaint in Intervention] … shall relate back to the filing date of the [Relator's complaint], to the extent that the claim of the Government arises out of the conduct, transactions, or occurrences set forth, or attempted to be set forth, in the prior

[10] The Complaint plainly alleges that these physicians were in a position to make decisions reagarding the Surgical Supplies. The United States is aware that Dr. Richard D. was *the* primary decisionmaker for Bay, and could amend its Complaint to explicitly state what is already a reasonable inference if necessary.

complaint of that person." [11] Here, the United States' Complaint plainly arises out of the same "conduct, transactions or occurrences" as the relator's original complaint. 31 U.S.C. 3731(c). In accordance with the plain language of the statute, because the United States had not learned of the right of action within three years of the time the relator filed his original complaint, and because the United States' complaint relates back to the time of the relator's original complaint, the United States can pursue claims dating back ten years from the time the original complaint was filed. Multiple courts interpreting the FCA after the FERA amendments have adopted this analysis. *See, e.g., United States ex rel. Sansbury v. LB & B Associates, Inc.*, 58 F. Supp. 3d 37, 52 (D.D.C. 2014) (applying this analysis to give the United States ten years back from the filing of the relators' complaint); *United States ex. rel. Dresser v. Qualium Corp.*, 5:12-CV-01745-BLF, 2016 WL 3880763, at *9 (N.D. Cal. July 18, 2016) (same).

Defendants do not contest that the United States' complaint relates back to the filing of the Relator's original complaint. Brief at 24 (citing 31 U.S.C. 3731(c)). Nevertheless, in support of the position that claims extending more than six years earlier than the Relator filed his Complaint are barred, Defendants have argued that the ten year limitations period applies only where the United States files its own Complaint in Intervention within three years of the Relator's initial filing. For support, they cite to a footnote in *United States ex rel. Frascella v. Oracle Corp.*, 751 F. Supp. 2d 842, 849 n.3 (E.D. Va. 2010), which

[11] Because the present version of this provision was added when the FCA was amended in 2009 by FERA, and applies retroactively, post-FERA cases addressing the relation-back issue are far more relevant to this analysis.

included a bare assertion without any rationale for this assertion, and an off-hand comment in *United States ex rel. Robinson-Hill v. Nurses' Registry & Home Health Corp.*, No. 5:08-145-KKC, 2012 WL 4598699, at * 3 (E.D. Ky. Oct. 2, 2012), where the Court stated, without explanation, that the ten year tolling provision in the statute was not relevant Notably, neither of these courts engaged with the statutory language or provided any insight as to why they might depart from the plain meaning of that language or from other precedent (and it is not at all clear that the reference in *Robinson-Hill* even related to this issue) (Brief at 24 n.18). In light of the clear statutory language, the precedent supporting the United States' position, and the principle affording the United States the benefit of doubt even if the scope of the statute of limitations were ambiguous, the United States can assert claims ten years back from the filing of the relator's original complaint.

D. COMMON LAW CLAIMS

The United States' common law claims for unjust enrichment and payment by mistake are plainly governed by federal common law. *See, e.g., United States v. Kimbell Foods, Inc.*, 440 U.S. 715, 726 (1979). In a case involving the Medicare program, the Eighth Circuit has held that federal common law governs "the determination of the rights of the United States under a nationwide program." *United States v. Applied Pharmacy Consultants, Inc.*, 182 F.3d 603, 606 (8th Cir. 1999). In *Applied Pharmacy,* the court applied Arkansas law after acknowledging that federal common law was controlling because "[t]here is no federal statute on the subject, however, and no reason to suppose that the common law of Arkansas would, in the present context, be in any way inconsistent with federal interests." 182 F.3d at 606. By contrast, in this case, federal law is clearly

controlling, in light of the AKS' application to this matter. *See Stone v. United States*, 286 F.2d 56, 59 (8th Cir. 1961) ("it is clear that federal rights are governed by controlling federal law."); *Cairns*, 2015 WL 590325, at *5; *United States v. Rogan*, 459 F. Supp. 2d 692, 721 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008).[12]

1. Payment by Mistake

"Where monies are erroneously paid by agents of the United States, whether the error be one of fact or law, the Government may always recover the money improperly paid." *Stone v. United States*, 286 F.2d 56, 58–59 (8th Cir. 1961). The United States need not show that the defendants knew that the payments were mistaken. *See, e.g., United States v. Mead,* 426 F.2d 118, 125 n. 6 (9th Cir. 1970). The Government must show that the Medicare program made payments under an erroneous belief which was material to the decision to pay." *Id.* at 124. This is precisely what is alleged here. The United States believed that the claims submitted to Medicare were properly payable, but they were not, because a material condition, the absence of a kickback tainting the claim, was not satisfied. Defendants are also incorrect that payment-by-mistake claims can only be brought against the entity that receives the funds from the government. *See, e.g., LTV Educ. Sys., Inc. v. Bell*, 862 F.2d 1168, 1175 (5th Cir. 1989) ("government is entitled to obtain repayment from a third party into whose hands the mistaken payments flowed where that party

[12] Pursuant to 31 U.S.C. 3731(c), the United States' common law claims relate back to the filing of the Relator's original complaint, for the same reasons discussed above.

participated in and benefitted from the tainted transaction."); *Mead*, 426 F.2d at 120, 124-25.[13]

2. Unjust Enrichment

Unjust enrichment under federal common law occurs where "the person sought to be charged is in possession of money or property which in good conscience he should not retain, but should deliver to another..." *Rogan*, 459 F. Supp. 2d at 721. The test set forth in the *Ventura* case cited by Defendants (Brief at 25) is a Minnesota state law test; because federal common law applies, it is inapposite. Next, contrary to Defendants' suggestion, nothing prohibits the United States from pleading its common law claims in the alternative. *United States v. R.J. Zavoral & Sons, Inc.*, 894 F. Supp. 2d 1118, 1127 (D. Minn. 2012); *United States v. Crumb*, CV 15-0655-WS-N, 2016 WL 4480690, at *18 (S.D. Ala. Aug. 24, 2016) (finding it "commonplace" for the government to plead payment by mistake and unjust enrichment alongside FCA claims, and noting "federal courts have routinely allowed common-law claims and FCA claims to coexist."). Finally, with respect to Defendants' argument regarding allegations pertaining to unjust enrichment, the Complaint alleges that Defendants were unjustly enriched because they obtained money for Surgical Supplies sales by virtue of the kickbacks, in violation of the AKS. The Complaint is replete with such allegations, as discussed above.

[13] The two cases relied upon by Defendants mistakenly apply Missouri state law, and are therefore inapposite. (Brief at 28-29).

CONCLUSION

For the foregoing reasons, the United States respectfully requests that Defendants' motion be denied.

Dated: May 31, 2018

Respectfully submitted,

GREGORY G. BROOKER
United States Attorney

s/ Chad A. Blumenfield

BY: CHAD A. BLUMENFIELD
Assistant U.S. Attorney
Attorney I.D. No. 387296
BY: BAHRAM SAMIE
Assistant U.S. Attorney
Attorney ID Number 392645
600 U.S. Courthouse
300 South Fourth Street
Minneapolis, MN 55415
(612) 664-5600

Attorneys for Plaintiff United States